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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/508,833      | 04/14/2005  | Ken-ichi Yamakoshi   | 004476.00033        | 8095             |

22907 7590 08/24/2006

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| EXAMINER |
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LIN, JACK

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| ART UNIT | PAPER NUMBER |
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3768

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/508,833 | <b>Applicant(s)</b><br>YAMAKOSHI, KEN-ICHI |  |
|                              | <b>Examiner</b><br>Jack Lin          | <b>Art Unit</b><br>3768                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/23/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed on September 23, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Specification***

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

3. Claims 1 and 2 are objected to because of the following informalities:

Claim 1, line 3 – “waveforms” should be changed to “wavelengths” to be consistent with the other claims.

Claim 1, line 5 – “reflecting thereon” should be changed to “reflected therefrom”.

Claim 1, line 14 – “blood constituents” should be changed to “blood constituent concentrations”.

Claim 2, line 8 – “bloods” should be changed to “blood samples”.

Appropriate correction is required.

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The originally filed claims did not include claim 16, but did include claims 17-25. Therefore, misnumbered claims 17-25 have been renumbered 16-24. Applicant should update dependencies accordingly. Applicant is advised that the claims referred to in this office action refers to the renumbered claims 16-24.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4-8 and 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the range of concentration" in line 4 and "the physiological concentration range" in lines 4-5, Claim 7 recites the limitation "the active spectroscopy" in line 4.

Claim 8 recites the limitation "the active spectroscopy" in lines 2-3.

Claim 10 recites the limitation "the multi-regression analyzing model" in lines 2-3.

Claim 11 recites the limitation “blood constituents of the plural whole blood samples” in lines 2-3 and “the physiological concentration range” in line 5.

Claim 14 recites the limitation “the active spectroscopy” in line 4.

Claim 15 recites the limitation “the active spectroscopy” in lines 2-3.

Claim 16 recites the limitation “the plural whole blood samples” in lines 2-3.

Claim 18 recites the limitation “the plural whole blood samples” in lines 2-3.

There are insufficient antecedent basis for these limitation in the claims.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Mendelson et al. (US Patent 5,372,135). Mendelson et al. discloses the same invention including a light source for irradiating light containing plural wavelengths (column 4, lines 11-13), light detectors for detecting light transmitted through the living body (column 4, line 41), and a computer (column 4, lines 61-62) that serves as a spectrum analyzer (column 4, lines 61-62), a spectrum subtraction generator (column 4, lines 45-50), and a blood constituents predictor that outputs the concentration of blood constituents (column 4, lines 63-64). Mendelson et al. also discloses a method of using the blood constituents measuring instrument (column 4, lines 10-64).

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Mendelson et al. further teaches an embodiment that performs measurements based on natural pulsations of a subject's blood (column 6, lines 16-63 and Figure 6).

Regarding Claims 2-4, 10-11, 16-18, 20-21, and 23-24, Mendelson et al. discloses using a multi-regression analyzing model (column 5, line 14) with data from samples having known blood constituent concentrations (column 6, lines 39-44). The multi-regression analyzing model includes PLS and PCR (column 5, lines 17-23). Blood inherently contains albumin in a concentration of 3.0 – 6.0 g/dl (see for example Evans et al., US Patent 5,571,723, column 2, lines 40-41). Additionally, blood inherently has different hematocrit values.

Regarding Claims 5-6 and 12-13, Mendelson et al. discloses using light having a wavelength band of 1100-2500 nm (column 6, line 24).

Regarding Claims 7-8 and 14-15, Mendelson et al. discloses using an active spectroscopy to separate light from the light source prior to transmitting through the body (column 4, lines 15-26).

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ishikawa et al. (US Patent 5,522,388) discloses a pulse spectrometer to analyze blood component concentrations. Kley et al. (US Patent 6,172,743 B1) discloses a device for non-invasively measuring an analyte within the body that includes using filters to provide a selected light spectrum. Caro (US Patent 5,348,003) discloses a method and apparatus for determining the concentration of analytes in complex materials that includes using a light modulator to temporally modulate light.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL  
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ERIC F. WINAKUR  
PRIMARY EXAMINER